User's Manual

Quattro

⚠ **Read this manual carefully before using Quattro.**

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SYMBOLS USED

The graphic symbols used on this device and on this manual refer to the UNI EN ISO 980 Law, CEI EN 60601-1, RAEE Law and 2002/96/ECC Directive.

SYMBOL	DESCRIPTION
	Serial Number
	Device with BF parts
	Class II device
	Warning, read the instructions before using the device. This symbol could also be used as a “Warning” symbol
	Read the instructions of use
	Manufacturer
	Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary following the 2002/96/EC Law of the European Parliament and Council of the European Union about the disposal of e-waste.

The Quattro device has been tested in reference to the EN 60601-1 and the EN 60601-1-2 Law. If the user connects the Quattro device to any other unauthorized device following the EN 606011 and EN 60601-1-2 Laws, he/she has to ensure that the combined use of the two devices follows the laws above mentioned.

Otherwise OT Bioelettronica shall not be held liable for accidents and/or injuries to persons or damage. For the features of the software, please read the Software Manual.

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1. GENERAL DESCRIPTION

The Quattro is a 4-channel surface electromyographic (EMG) device. This system has been designed to detect surface electromyography signals (sEMG) from skeletal muscles with the use of the surface electrodes.

The information detected from electrodes is then transferred to a PC with a wired connection (USB) or with a wireless connection (Bluetooth). The Quattro works with a software named OT BioLab in order to display and process the data. This software is part of the Quattro system and it is also possible to download it for free on the website www.otbioelettronica.it in the Downloads section.

2. INTENDED USE

Quattro has been designed to be used as an electromyography to detect the activity of skeletal muscles up to 4 muscles simultaneously.

⚠ **The device is not intended to be used near inflammable anaesthetics.**

3. PLACE OF USE

Quattro is intended to be used primarily as a laboratory device and secondly as a hospital device: as a home device, the patient uses the device at home during the day and as a hospital device the operator uses the information detected from it in order to make a diagnosis.

4. USER PROFILE

USER: Specialized operator

a) Knowledge: Minimum. Basic notions about the human body
b) Languages: Italian and/or English
c) Experience: Minimum. Minimum training about the device use
d) Handicaps:
    - Maximum reduction of the hearing of 40% with residual hearing at 60%;
    - Maximum sight reduction of 40% with residual sight at 60%

KIND OF PATIENT:

a) Age: >= 15 years
b) Weight: Not Important
c) Health: No cardiovascular problems no pacemakers
d) Nationality: not relevant

5. SAFETY CAUTIONS AND WARNINGS

The use of Quattro is forbidden in the following conditions:

- Simultaneous use of electro surgery systems, shortwave or microwave therapy or near these type of devices;
- Unsound mind patient;
- The device is damaged;
- Near inflammable anaesthetics with air, oxygen or nitrous oxide.
- To make an electrocardiographic exam
- Pacemaker users

These warnings must be followed:

- Contact immediately the manufacturer if foreign materials (liquids, etc.) come into contact with the device.
- If the device falls in to the ground or something similar happens, check if the device is undamaged. In case of doubt, contact the manufacturer.

The Quattro could be sensitive to electromagnetic interferences of other devices that could alter its electromyography measurements and consequently the physiological variables calculated on the basis of the information detected. For this reason, do not use it near devices that could cause the problems described above, for example mobile phones, instruments with power transformer, etc.

- The operator must be sure that the battery of the device is completely charged following what is indicated in this User's Manual before to give the device to the patient.
- The device must be kept out of reach of children or unsound mind patient
- Do not clean the device using acetone, ether, freon, oil products or any other solvent
- Do not use soap or water on the connector pin
- Do not clean Quattro or connection cables with water, in autoclave or steam cleaning

The device must not be used in any other way than indicated in these instructions

6. CONTENT OF THE QUATTRO KIT

ACCESSORIES AND DOCUMENTS			
REF	Description	Features	
CUSB03	USB connection cable to recharge internal battery and for PC connection.	**UNSTERILE**	**REUSABLE**
ADx5JC	4 bipolar electrodes connection adapter	**UNSTERILE**	**REUSABLE**
TRBELT01	Belt holder	**UNSTERILE**	**REUSABLE**

⚠ The accessories of the machine indicated above are to be considered as part of the device itself, so they are not subject to CE marking.

ACCESSORIES NEEDED BUT NOT INCLUDED IN THE STANDARD EQUIPMENT			
REF	Description	STERILE	SINGLE-USE
CODE401500 - 501500	Concentric Detection electrodes	**NO**	**YES**
CDE	Bipolar detection electrodes	**NO**	**YES**
CDE	Bipolar detection electrodes	**NO**	**YES**

⚠ **Use of the equipment accessories and/or CE** accessories of the OT Bioelettronica to be used for the detection of the electromyography signals.

7. DETAILED DESCRIPTION

Controls, indicators and connectors of the Quattro are shown in Fig. 1 and described in the following sections.

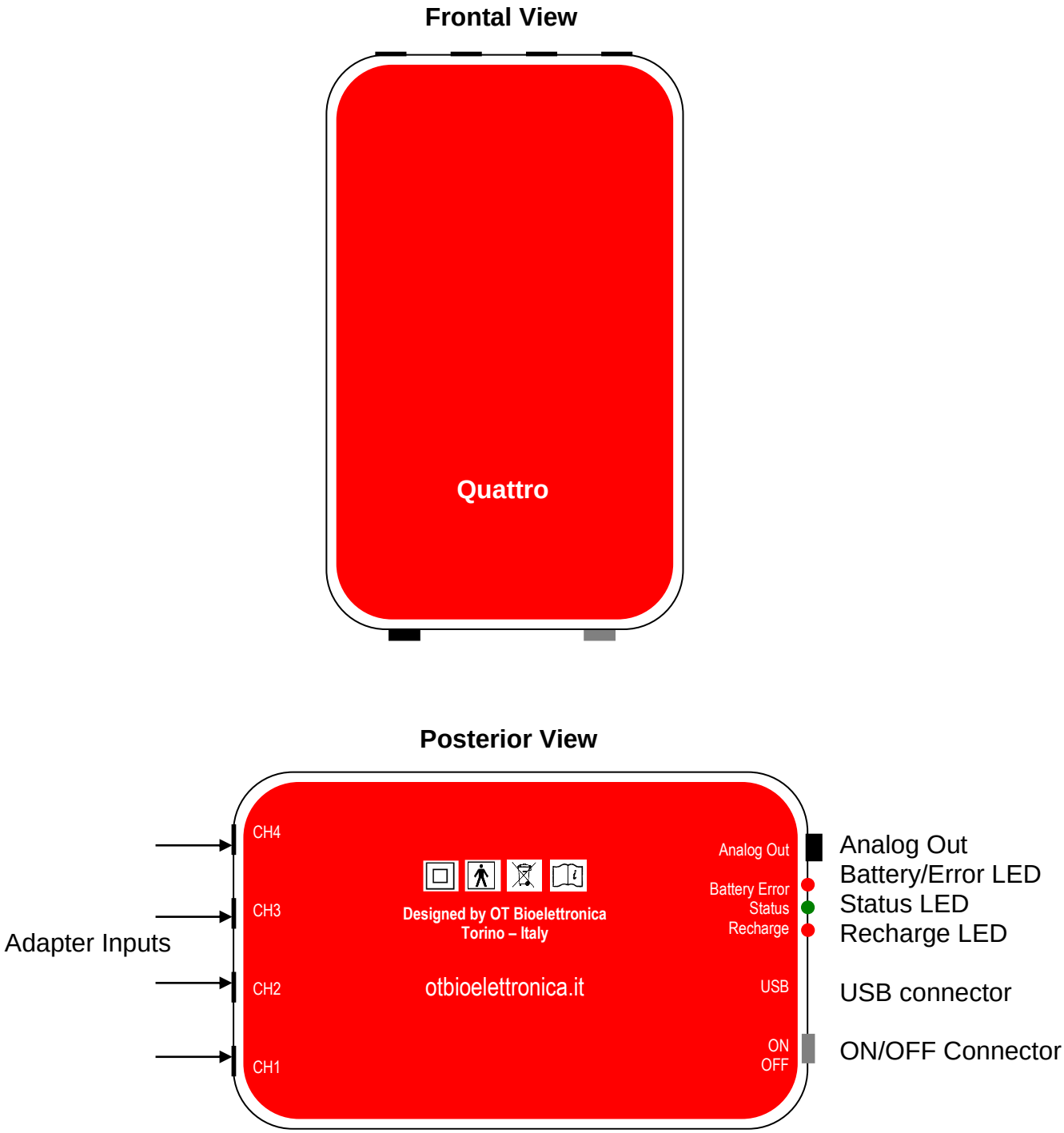


Fig. 1: *Front view and Back view of the Quattro*

Description of controls, indicators and connectors shown in fig.1:

- Adapters Inputs: These for inputs allow the connection of electrode adapters ADx5JC.

- **Analog Out**: At this connector are available the 4 EMG signals amplified and filtered in an analog modality after octocoupling.

- Battery/Error LED: This red LED is normally off, it switch on when the battery is empty and when there is some loose of data during Bluetooth transmission.

- Status LED: This LED flashes blue when Quattro is working.

- Recharge LED: This red LED switches on to indicate that battery are under charge. It switch off when battery are fully recharged.

- USB connector: this connector is used to recharge battery and to transfer data from Quattro to the PC.

- **ON/OFF switch:** With this switch is possible to turn off and on the Quattro system.

When the system is connected via USB to the PC it is automatically on, independently of the ON/OFF switch position.

Electrode adapters: to detect the electromyography signals produced by muscles, the Quattro needs at least one of the four adapters ADx5JC connected.

Each one of ADx5JC adapters ends with a jack connector in one termination; the other termination can be composed by different connectors according to the selected electrodes to place on the skin.

⚠**To make a proper measurement the adapter ADx5JC with snap-on reference must be connected to Quattro device.**

USB cable: charge battery cable

The Quattro device has as accessory a USB cable called CUSB03 (USB – miniUSB). This cable allows charging Quattro by its connection to a USB PC port or to a power supplier that incorporates an USB output.

System Requirements for PC connection

1. Windows Operating system for PC (Windows XP, Vista, Windows 7, Windows 8)
2. USB port to recharge the Quattro equipment

Behaviour of the device during battery charge process

During the battery charge process the red Recharge LED, located on the Quattro right side (posterior view) becomes red till the end of the recharge process, when the battery is fully charged the red LED switches off.

⚠ **Charge the device for at least 2 hours before to use it.**

Application and acquisition with the Quattro device

To use the Quattro system properly, please follow these instructions:

- connect electrode adapter/adapters (ADx5JC) to the Quattro device;
- take the electrodes and apply them, that means in direct contact with the investigated muscles;
- take the snap-on connector of the reference cable and connect it to the reference electrode displaced on a point without EMG activity.
- wear the chest belt;
- connect the electrode adapter to the interested electrodes;
- switch on the Quattro device using the ON/OFF switch;
- connect the USB cable CUSB03 (for wired recordings)
- run the OT BioLab software and proceed with the signal acquisition (see OT BioLab SW manual)
- at the end of the measurement session remove the electrodes and disconnect them. Disconnect the electrode adapter from the Quattro device, and then put the device and its accessories back in its packaging. Throw away the single-use electrodes.

⚠ **The single-use concentric electrodes cannot be reused.**

8. TROUBLESHOOTING

This section describes the most common problems that may be found by Quattro users.

Problem Description	How to deal with it
After the Quattro switch-on the Bluetooth connection is not available	Check the Battery charge
The red LED Error is switched-on	Battery empty, so recharge it or Data transmission error, please move near to the PC, tablet, smartphone with Quattro device

9. QUATTRO MAINTENANCE AND STORAGE

Quattro has to be used, transported and stored in the following conditions:

Temperature:	**from 10°C to +40°C**
Maximum relative humidity:	**from 30% to 75%**
Atmospheric pressure:	**from 700 hPa to 1060 hPa**

It is recommended to turn off the Quattro at the end of every session.
The Quattro should be stored with all the enclosed accessories on a safe place far from all conditions described in the Warnings section of this manual. The Quattro does not need any particular maintenance procedure to work. To maintain the battery efficiency, recharge the device before every use and check regularly the efficiency status of the battery.

⚠ If during the use and after the battery charging the battery lasts less than 1 hour, contact the manufacturer to check the electrical source itself.

Cleaning the device: At the end of every use, please clean the Quattro with a clean cloth.

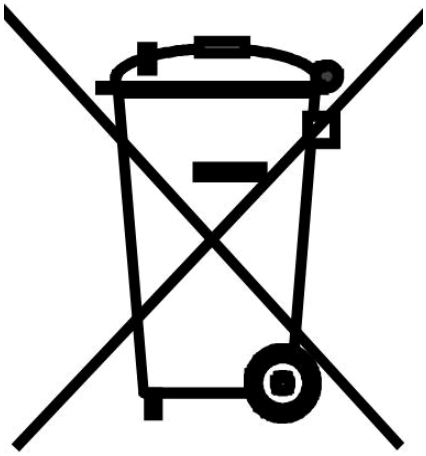
- ⚠ Do not clean the Quattro using acetone, ether, freon, oil products or any other solvent;

  ⚠ Do not use soap or water on the connectors pin contacts.
- ⚠ Do not clean the Quattro or its cables with water, in autoclave or with steam cleaning**.**

⚠ **WARNING: clean electrodes adapter cable only with hospital disinfectants before every use to avoid microbial contamination between patients and healthcare professionals.**

Product Disposal

The Quattro contains electronic parts that must be disposed of as e-waste. Dispose the device and the accessories following local regulations. Follow the disposal regulations of your country in order to ensure the correct disposal of the Quattro and its accessories. For further information about the disposal of this device, contact the Environment Department and local authority.



⚠ **Warning**: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment of necessary, following the 2002/96/EC of the European Parliament and European Council on waste electrical and electronic equipment.
(WEEE). The regulation is not valid in case of corrupted product.

Life span of the device

The Quattro system is produced in order to last if the use and maintenance conditions indicated in this User's manual are followed. The life span of the device is determined by the life span of the battery (5 years). After this period it is recommended to take the device to the manufacturer every two years.

10. TECHNICAL SPECIFICATIONS

The Quattro device is a battery system designed following the medical regulations in order to ensure the patient safety.

The signal amplified by the system is transferred to a PC by wired USB cable or by wireless (Bluetooth) modalities.

In table 1 technical specifications of the Quattro device are reported.

Model	Quattro
Classification	Battery system
Degree of Protection	IP32
Case	Plastic case
Power Supply	3,7V Battery, rechargeable
Battery time	8 Hours (full charge)
Charging time	2 hours
Class	II
Numbers of Channels	4
Dynamics	0 ÷ 3.3 mV_{PP}
Band	10 ÷ 500Hz
Input Noise	< 2 μV_{RMS}
Amplification	150 V/V
Input impedance	> 10^9 Ω on the entire bandwidth
CMRR	>96 dB
Output Dynamics	0 ÷ 3.3 V
A/D converter resolution	16 bits
Wireless transmission modality	Bluetooth
Wired transmission modality	USB
Sampling rate	1.024 Hz
Dimensions	59 x 95 x 20 mm
Weight	90g

TAB. 1: *Technical Specifications of the Quattro*

CUSTOMER SERVICE

Quattro has no parts that can be replaced or repaired by the user; contact the distributor for assistance so that he/she can repair or replace the products under warranty.

Maintenance and replacement of parts, modifications and/or reparations made by unauthorized Companies and/or operators by OT Bioelettronica will forfeit entitlement to warranty.
OT Bioelettronica denies any and all responsibility for damages caused directly or indirectly as a result of maintenance, replacement of parts, modifications and/or reparations made by Companies and/or operator that are not authorized by the OT Bioelettronica
Quattro does not need any prior maintenance.

WARRANTY

OT Bioelettronica ensures that every new product has no defects due to materials and labour and will repair and/or replace in warranty products used following the intended use and used in the use conditions described in this manual.

Warranty lasts **2 years** only after filling and signature of the warranty application form that you find below.

Warranty conditions: the obligations of OT Bioelettronica following the warranty are limited exclusively to what follows:
- reparation will be made by and no later than 30 work days after the receipt of the product and only after the verification that the malfunctioning is not due to inadequate or inaccurate use, maintenance and /or reparation.

If OT Bioelettronica verifies that the malfunctioning is not due to inadequate or inaccurate use or unauthorized maintenance/reparation, the reparation costs (materials and labour) will be invoiced only after acceptation of the budget of reparation by the owner.

These warranty conditions substitute all the other warranty conditions, explicit or implicit, included, but not within limits of the general conditions specified in the international sale regulations.

OT Bioelettronica reserves the right to refuse the reparation of any products sent by the user for reparation; this refusal will be conveniently explained. The only obligation of OT Bioelettronica is that of returning the product to the user at its own expenses.

Manufactured by:

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